UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,219	02/27/2004	Jean-Luc Jestin	248628US0X	5396

22850 7590 03/02/2007

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/02/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/787,219	JESTIN ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) *9-16 and 23-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,17-22,78 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/06 & 2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-22, 78 and 79, mutation M484 and the sequence depicted in SEQ ID NO: 19 and 20 in the reply mailed 12/26/2006 is acknowledged. The traversal is on the ground that the Office has not shown that a burden exists in searching the entire application. Applicant states that a search of all the claims would not impose a serious search burden on the Office. Applicant traverses the election of Species requirement on the ground that the Office has not provide any reasons, whatsoever, to support the conclusion of patentable distinctness. Applicant asserts that rather the Office has merely stated the conclusion. Applicants state that they do not make any statement regarding the patentable distinctness of the species, but note that for restriction to be proper, there must be a patentable difference between the species as claimed. Applicant states that the Office has not provide any reasons or examples to support a conclusion that the species are indeed patentably distinct Applicant states that accordingly, the restriction requirement is improper and the election of species is for examination purposes only. Finally, Applicant states that with respect to the elected species, Applicant respectfully submits that should the elected species be found allowable, the Office should expand it search to the non-elected species. Applicant states that the Office has failed to meet the burden necessary in order to sustain the Restriction and election of Species requirement. Applicant request withdrawal of the restriction and Election of Species requirement is respectfully requested.

2. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In response to Applicant's arguments that it would not be a serious burden to the Examiner to search the different inventions together, the Examiner respectfully disagree. The examiner maintains that a serious burden exist because the searches of the different inventions are not coextensive.

The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases which require a search burden. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers that had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 80% to 97.5% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of groups I with the invention of Group II. In regards to searching the invention of Group I with that of Groups III through V, it is noted that the invention of Group I encompasses molecules which are claimed in terms of percent identity in regard to reference sequence SEQ ID NOS and mutations, which may or may not be required for a search of Groups III through V. In contrast, the search for groups III-V would require a text search for the

method of reverse transcribing RNA or a method of identifying mutant polypeptides or a method of obtaining an enzyme in addition to an polynucleotide search or mutation search related to a particular sequence. Prior art which teaches a polynucleotide that is 80% identical to SEQ ID NO: 26, for example, would not necessarily be applicable to the method of using the sequence. Moreover, even if the polynucleotide product were known, the method of use may be novel and unobvious in view of the preamble or active steps.

In response to Applicant's arguments concerning a species election, Applicant is reminded that the restriction requirement concerning the sequence election is *not* a species election but an election requirement regarding the different sequences as they relate to the different mutations. Therefore, Applicant's arguments concerning a species election are deemed moot. As stated in the prior Office action, MPEP 803.04 states:

> "[N]ucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. The sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence or amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 eq seq. By statute, "[i}f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the invention". "35 U.S.C. 121." Pursuant to this statute, the rules provided that "[i]f two or more independent and distinct invention are claimed in a single application, the examiner in his action shall require the Applicant....to elect that invention to which his claim shall be restricted". 37 CFR 1.142(a). See also 37 CFR 1.141(a)".

In this case, the mutations are structurally distinct chemical compounds that are unrelated to one another and have different effects. Specifically, the chemical structure of the molecule comprising the mutation M484V is structurally and chemically distinct from the molecule comprising the mutation W550R or the mutation comprising A331. With regards to different effects, the molecules comprising the different mutations have different polymerase activity. Therefore, the sequences are capable of separate use, which is clearly evident in this application both by the separate claiming and because each mutation can be separately screened and function irrespective of the other mutation to effect polymerase activity. Applicant's arguments are sufficient to remove the restriction requirement.

The restriction requirement is therefore made FINAL. Accordingly, the claims 1-8, 17-22, 78 and 79 are discussed in this Office action. The claims 9-16, 23-77 are withdrawn from prosecution as being drawn to a non-elected invention.

Specification

3. The disclosure is objected to because of the following informalities:

(a) The use of the trademark Expedite at paragraph 0196 has been noted in this application. It should be *capitalized* wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 1-8, 17-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; *Diamond v. Chakrabaty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "an isolated and purified protein or nucleic acid". It should be noted that a recombinant enzyme/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

6. Claim 22 is rejected under 35 USC 101 because the claimed invention is directed to a non-statutory subject matter. The specification states that the invention relates to host cells, which includes any cell having the capacity to be infected or transfected by phages or vectors comprising the polynucleotide sequences encoding the enzymes described therein. Thus, the cell could be present or intended to be present in a human being, said cell becoming integrated into the human being and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter. As such the recitation of the limitation "non-human" or "isolated host cell' would obviate this rejection. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 78 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification lacks deposit information for the inserts recited in claims 78 and 79. The specification at paragraphs 0150 through 0159 only recite that the inserts are deposited as CNCM in the Collection Nationale de Cultures de Microorganismes (CNCM) on February 27, 2004. The specification provides no extensive information for one of skill in the art to produce cell recited therein. Therefore, the specification is not considered sufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met for the claimed deposit. If a deposit is made under the terms of the Budapest Treaty, than an affidavit or declaration by Applicant(s), or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, than in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by

affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) During the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) The deposit will be maintained in a public for the enforceable life of the patent;

(d) A test of the viability of the biological material at the time of the deposit (see 37 CFR 1.807); and

(e) The deposit will be replaced if it should ever become inviable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each Member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository along with a statement verifying whether or not the deposit was made under the Budapest Treaty is required to meet the requirements of a deposit.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 18 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

(a) Claim 18 is indefinite at "complementary" because "complementary" has not been defined in the specification or claims. Additionally, the term "complementary" can mean a polynucleotide complementary to a small region of a given DNA or alternatively complementing the entire region. Accordingly, as written, the metes and bounds of the claims cannot be determined. It is suggested changing "complementary" to "a fully complementary..." or some other language that is supported by the specification as originally filed.

(b) Claim 78 is indefinite in that it fails to point out what is included or excluded by the claim language the number. This claim is an omnibus type claim. Specifically, it is unclear if the limitation "the number" is in reference to "the phage insert" or in reference to the "deposit number in CNCM" or in reference to a separate entity. Accordingly, it cannot be determined Applicant's intent.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-8, 17-22 and 78 and 79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 14-18, 65 and 66 of copending Application No. 10/590810. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims 1-8, 17-22 and 78 and 79 of the instant invention and the claims 1-7, 14-18, 65 and 66 of copending application 10/590810 are drawn to a purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having at least 80% identity to nucleotide residues of SEQ ID NO: 26, and wherein the polypeptide has at least one mutation in A331, L332, D333, S335, Y334 and M484 and wherein said polypeptide has DNA polymerase activity. The claims are further drawn to a vector; host cell and DNA insert comprising the purified polynucleotide or polypeptide.

The claims 1-7, 14-18 and 65 and 66 of copending application '810 only differ from the instant invention in that they further recite wherein the polypeptide has a mutation in amino acids 13-555 of SEQ ID NO: 26. Thus, the claims 1-8, 17-22 and 78-79 of the instant invention falls entirely within the scope of the claims the claims 1-7, 14-18, 65 and 66 of copending application '810. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. Miller, 151, U.S. at 198; See Stanley, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the species of the patented invention. Cf., Titanium metal corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-8, 17-22 and 78 and 79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 14-18, 65 and 66 of copending Application No. 11/065,943. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical,

but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claims 1-8, 17-22 and 78 and 79 of the instant invention and the claims 1-7, 14-18, 65 and 66 of copending application 11/065943 are drawn to a purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having at least 80% identity to nucleotide residues of SEQ ID NO: 26, and wherein the polypeptide has at least one mutation in A331, L332, D333, S335, Y334 and M484 and wherein said polypeptide has DNA polymerase activity. The claims are further drawn to a vector; host cell and DNA insert comprising the purified polynucleotide or polypeptide.

The claims 1-7, 14-18 and 65 and 66 of copending application '943 only differ from the instant invention in that they further recite wherein the polypeptide has a mutation in amino acids 13-555 of SEQ ID NO: 26. Thus, the claims 1-8, 17-22 and 78-79 of the instant invention falls entirely within the scope of the claims 1-7, 14-18, 65 and 66 of copending application '943. As the court stated in *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993), " a second application-- "containing a broader claim, more generical in its character than the specific claim in the prior patent"--typically cannot support an independent valid patent. Miller, 151, U.S. at 198; See Stanley, 214 F.2d at 153. Thus, the generic invention, as noted above is "anticipated" by the

species of the patented invention. Cf., Titanium metal corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (holding that an earlier species disclosure in the prior art defeats any generic claims). This court's predecessor has held that, without a terminal disclaimer, the species claims preclude issuance of the generical application. "*In re Van Ornum*, 686 F.2d 937, 944, 214 USPQ 761, 767 (CCPA 1982); *Schneller*, 397 F.2d at 354".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Prior Art

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lawyer et al (cited on IDS filed 02/1994) teach an isolated and purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having 96.4% identity to the sequence of SEQ ID NO: 26 (see page 6429), wherein said polypeptide has DNA polymerase activity. Lawyer et al differs from the instant invention in that the reference does not teach wherein the encoded polypeptide has at least one mutation in amino acids 738-767 or at positions M484V or M484T (which relates to position 761).

Li et al (PNA, vol. 96, 9491-9496, August 1999) teach an isolated and purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having 96.4% identity to the sequence of SEQ ID NO: 26 (see entire reference), wherein said polypeptide has DNA polymerase activity and wherein said

polypeptide has at least one mutation in amino acids 660 to 667. Li et al differs from the instant invention in that the reference does not teach wherein the encoded polypeptide has at least one mutation in amino acids 738-767 or at positions M484V or M484T (which relates to position 761).

Wang et al teach an isolated and purified polynucleotide which encodes a thermostable polypeptide comprising an amino acid sequence having 96.4% identity to the sequence of SEQ ID NO: 26 (See SEQ ID NO: 11), wherein said polypeptide has DNA polymerase activity. Wang et al differs from the instant invention in that the reference does not teach wherein the encoded polypeptide has at least one mutation in amino acids 738-767 or at positions M484V or M484T.

Conclusion

15. Claims 1-8, 17-22, 78 and 79 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Wilder

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637

2/26/07